THE HONORABLE MARSHA J. PECHMAN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

KENNETH McGUIRE, On Behalf of Himself and All Others Similarly Situated, Plaintiffs, v. DENDREON CORPORATION, et al., Defendants.	CASE NO.: C07-800-MJP Consolidated Class Action **DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT IN *MCGUIRE v. DENDREON* AND *MOUNTANOS v. DENDREON*** **Note on Motion Calendar: July 30, 2010** **ORAL ARGUMENT REQUESTED**
This document relates to: All Actions.	
WILLIAM MOUNTANOS, PETER MOUNTANOS, JAMES RYE, and TYRONE REMINGA, Plaintiffs, v. DENDREON CORPORATION, a Delaware Corporation, MITCHELL GOLD, and DAVID URDAL, Defendants.	CASE NO.: C09-426-MJP

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Now that discovery is closed, plaintiffs must provide evidence to support their claims. They cannot do so. Uncontroverted facts demonstrate that defendants did not make a false or misleading statement, and that the statement that plaintiffs challenge has no causal link to the loss that plaintiffs claim. Lacking any genuine issue of material fact to establish these essential elements, plaintiffs cannot sustain their claim for securities fraud under Section 10(b) of the Securities and Exchange Act of 1934 ("Section 10(b)"). Defendants Dendreon Corporation ("Dendreon"), Dendreon Chief Executive Officer Dr. Mitchell Gold, and Dendreon Chief Scientific Officer Dr. David Urdal thus ask the Court to grant summary judgment as to the first and second claims for relief in the Third Amended Complaint for Violation of the Federal Securities Laws ("Third Amended Complaint" or "TAC ¶ _") in *McGuire v. Dendreon*, No. 2:07-cv-00800-MJP, and the Amended Complaint ("MAC ¶ _") in *Mountanos v. Dendreon*, No. 2:09-cv-00426-MJP.

FACTUAL BACKGROUND

Plaintiffs' Section 10(b) claim now rests on a single statement: Dr. Urdal's opinion on March 29, 2007, that "we hosted a good inspection, I think." TAC ¶¶ 7, 71; MAC ¶¶ 7, 67; Ex. 1 at 5. Dr. Urdal's opinion referred to the pre-license inspection ("PLI," also referred to as "PAI") that the U.S. Food and Drug Administration ("FDA") held at Dendreon's New Jersey manufacturing facility in February 2007. TAC ¶¶ 5, 7; MAC ¶¶5, 7. The FDA conducted this PLI as part of its evaluation of the Chemistry, Manufacturing and Controls ("CMC") portion of Dendreon's Biologics License Application ("BLA") for Provenge, a revolutionary treatment for prostate cancer. TAC ¶¶ 2, 4, 42; MAC ¶¶ 2, 4, 35. Dendreon submitted the Provenge BLA in November 2006, and the FDA granted it priority review, setting a target action date of May 15, 2007 (often called the "PDUFA" date). TAC ¶ 3; MAC ¶ 3.

Dr. Urdal's statement was made during an analyst conference call immediately following a meeting by the FDA's Office of Cellular, Tissue and Gene Therapies Advisory Committee ("Advisory Committee"), which voted 17-0 that Provenge was reasonably safe, and 13-4 that there was substantial evidence of efficacy. TAC ¶ 66; MAC ¶ 63. This vote came despite the

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fact that concerns about the sufficiency of the Provenge clinical trials were disclosed at the Advisory Committee meeting and extensively debated. *See, e.g.*, Ex. 2 at 153-65; 162-65; 307-23; 343-47; 370-74; 386. This vote created expectations that Provenge would be approved in 2007, and the next day, the price of Dendreon stock rose from $5.22 to $12.93. TAC ¶¶ 65-68; MAC ¶¶ 62-64. However, on May 8, 2007, the FDA did not approve Provenge but, instead, issued a Complete Response Letter ("CRL"), indicating it needed additional information before approving the product. TAC ¶ 87; MAC ¶ 81. Following Dendreon's May 9, 2007 disclosure of the CRL, the price of Dendreon stock dropped from $17.74 to $6.33. TAC ¶ 11; MAC ¶ 11.

Plaintiffs allege that the 2007 PLI was not, in fact, a "good inspection" and that neither Dr. Urdal nor Dr. Gold, who also participated in the conference call, honestly believed that they had "hosted a good inspection." TAC ¶¶ 13, 72, 77; MAC ¶¶ 13, 68, 72. In addition, they allege that Dr. Urdal's statement was misleading because it did not mention that Dendreon was issued an FDA Form 483 at the conclusion of the PLI. TAC ¶¶ 13, 72; MAC ¶¶ 13, 68. Plaintiffs contend that because one of the 12 items listed in the CRL referred to "outstanding issues" from the PLI, the observations made in the Form 483 must have prevented FDA approval by the PDUFA date. TAC ¶ 13; MAC ¶ 13.

Following the receipt of the CRL in 2007, Dendreon completed an additional clinical trial ("D9920B" or "IMPACT") that confirmed the efficacy of Provenge and met the terms of a Special Protocol Assessment developed with the FDA. Ex. 3 at 11. On April 14, 2009, the day Dendreon announced the unambiguously positive results of this trial, the price of Dendreon stock rose from $7.30 to $16.99. Ex. 4 (press release announcing trial results); Ex. 5 (chart showing stock price increase). Dendreon submitted these results to the FDA on October 30, 2009, thereby finishing its "response" to the May 8, 2007 Complete Response Letter. Ex. 6 at 2. On April 29, 2010, the FDA approved Provenge on the strength of this new evidence of efficacy. Ex. 7 at 2.

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LEGAL STANDARD

I. PLAINTIFFS MUST OFFER EVIDENCE TO SUPPORT THEIR CLAIMS.

Summary judgment is proper where "no genuine issue as to any material fact" exists, such that "the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). "[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 256 (1986) (party must produce "significant probative evidence" sufficient to support a jury verdict). Summary judgment should be granted if a party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

The moving party bears the initial burden of demonstrating that no genuine material issue exists, or that the non-moving party lacks sufficient evidence to carry its burden. *Id*. at 323-25. Then, the non-moving party must set forth specific evidence demonstrating a genuine issue of fact, and produce evidence sufficient to establish the existence of the elements essential to its case. *See* FED. R. CIV. P. 56(e). In evaluating a summary judgment motion, the Court must construe the evidence and draw justifiable inferences in favor of the non-moving party. *Anderson*, 477 U.S. at 255. However, "muddled and hypothetical speculations" or "strained or inconclusive inferences" will not defeat summary judgment. *In re Adobe Sys., Inc. Sec. Litig.*, 787 F. Supp. 912, 918 (N.D. Cal. 1992) *aff'd mem. sub nom. Cloutier v. Adobe Sys.*, 5 F.3d 535 (9th Cir. 1993). Neither does "attorney argument" substitute for the factual showing necessary. *In re Remec Inc. Sec. Litig.*, No. 04-CV-1948-MMA, 2010 WL 1676741, at *37 (S.D. Cal. Apr. 21, 2010). Finally, sufficient evidence must be presented *before* trial – summary judgment cannot be defeated on the *hope* of developing evidence at trial. *T. W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

To defeat summary judgment, plaintiffs must show they have sufficient evidence to establish *each* element of a Section 10(b) claim: (1) a materially false or misleading statement;

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(2) scienter; (3) a connection with the purchase or sale of a security; (4) *both* transaction *and* loss causation; and (5) economic loss. *Metzler Inv. GMBH v. Corinthian Colls*., 540 F.3d 1049, 1061 (9th Cir. 2008). When the challenged statement is an opinion, plaintiffs must be able to show both objective and subjective falsity. *Rubke v. Capitol Bancorp Ltd*., 551 F.3d 1156, 1162 (9th Cir. 2009).

The evidence produced in discovery illustrates plaintiffs' difficulty in establishing a number of these elements. For example, deposition testimony, documents produced by defendants and made public by the FDA, and reports by experts with more than 40 years of combined FDA experience, support that it was objectively reasonable for Dr. Urdal to characterize the 2007 PLI as "good." The evidence also contradicts plaintiffs' speculation that defendants acted with scienter. Indeed, plaintiffs have still offered no coherent theory – and the evidence supports none – as to why defendants would seek to deceive Dendreon investors about the "true" results of the PLI, when there are no allegations that either the Company or Dr. Urdal, the person who made the challenged statement, profited in any way from the alleged deception.

In this motion, however, defendants focus on two elements: subjective falsity and loss causation. First, the undisputed evidence demonstrates that Dr. Urdal truthfully expressed his opinion about the PLI, in a way that he believed presented a fair overall characterization. Thus, summary judgment should be granted because plaintiffs cannot demonstrate that Dr. Urdal's statement was subjectively false or misleading. Second, plaintiffs cannot show a causal connection between the alleged misrepresentation and their loss. The price of Dendreon stock declined because the FDA did not approve Provenge in 2007, a decision that stemmed from the FDA's concerns over the sufficiency of the Provenge clinical trials. Even in the absence of the Form 483, plaintiffs would have experienced an identical loss. Thus plaintiffs are unable, as a matter of law, to demonstrate their loss was caused by the statement they challenge.

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II. THERE ARE NO FACTS INDICATING DR. URDAL'S STATEMENT WAS SUBJECTIVELY FALSE OR MISLEADING.

A. Plaintiffs must prove Dr. Urdal's opinion was subjectively false or misleading.

The only statement that plaintiffs challenge – "[W]e hosted a good inspection, *I think*"-is a statement of opinion. *McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 WL 5130042, at *5 (W.D. Wash. Dec. 5, 2008) ("*McGuire II*"). As such, plaintiffs must prove the statement is *both* objectively and subjectively false or misleading, in accordance with Supreme Court precedent that was adopted by the Ninth Circuit in *Rubke v. Capitol Bancorp*. *McGuire v. Dendreon Corp.*, 688 F. Supp. 2d at 1242-43 (W.D. Wash. 2009) ("*McGuire III*"); *Rubke*, 551 F.3d at 1162 (citing *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1095-96 (1991)). *Rubke* holds that to show subjective falsity, plaintiffs must prove that Dr. Urdal did not believe the opinion he expressed. *Rubke*, 551 F.3d at 1162, *affirming Rubke v. Capitol Bancorp, Ltd.*, 460 F. Supp. 2d 1124, 1146 (N.D. Cal. 2006) ("'A fairness opinion is objectively false if the subject matter of the opinion is not, in fact, fair, and is subjectively false if the speaker does not, in fact believe the subject matter.'") (quoting *Shurkin v. Golden State Vintners, Inc.*, No. C 04-3434 MJJ, 2005 WL 1926620, at *9 (N.D. Cal. Aug. 10, 2005.) The *Rubke* court cites to a district court decision that expounds upon this standard, requiring that plaintiffs show *knowing* falsity of opinions. *Rubke*, 551 F.3d at 1162, citing *In re McKesson HBOC, Inc. Sec. Litig.*, 126 F. Supp. 2d 1248, 1265 (N.D. Cal. 2000) (dismissing claim because plaintiffs did not plead that an opinion was "knowingly false"). Other circuit courts similarly demand that plaintiffs show *knowing* falsity of opinions. *See, e.g.*, *In re Credit Suisse First Boston Corp.*, 431 F.3d 36, 47 (1st Cir. 2005) (plaintiffs must plead "facts sufficient to indicate that the speaker did not actually hold the opinion expressed"); *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1131 (2d Cir. 1994) ("A statement of reasons, opinion or belief . . . can be actionable under the securities laws if the speaker knows the statement to be false."); *In re Merck & Co., Inc. Sec., Deriv. & ERISA Litig.*, 543 F.3d 150, 166 (3d Cir. 2008) (plaintiffs must show defendants "did not hold those opinions . . . in earnest"); *Nolte v. Capital One Fin. Corp.*, 390 F.3d 311, 315

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(4th Cir. 2004) ("[U]nder *Virginia Bankshares*, the complaint must allege that the opinion expressed was different from the opinion actually held by the speaker.")

Some courts examine subjective falsity in a manner that is similar to a scienter analysis. *See Remec*, 2010 WL 1676741, at *32 (applying *Rubke* to grant summary judgment because plaintiffs failed to show an opinion was not "grounded on . . . a genuine personal belief"). However, subjective falsity is distinct from scienter. First, although the subjective falsity standard has been applied to Section 10(b) claims, it has also been used in cases, such as *Rubke* itself, where the claims do not require a showing of scienter. *See Rubke*, 551 F.3d at 1162 (applying in Section 11 case); *McKesson*, 126 F. Supp. 2d at 1265 (applying in Section 14 case); *but see, e.g.*, *Shurkin*, 2005 WL 1926620, at *9 & n.7 (subjective falsity requirement applies in a Section 10(b) claim). Second, as discussed above, *Rubke* requires plaintiffs to show a speaker *knew* his opinion was false. *Rubke*, 551 F.3d at 1162 (citing cases). This is distinct from scienter, which can be established by either actual knowledge or "deliberate recklessness." *In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 977 (9th Cir. 1999). Thus, while inquiries into both subjective falsity and scienter explore a speaker's state of mind, they bear on distinct elements of a claim, and involve different standards of proof. *See, e.g.*, *In re Real Estate Assocs. Ltd. P'ship Litig.*, 223 F. Supp. 2d 1142, 1148-49 (C.D. Cal. 2002) ("Where a statement of opinion is claimed to be false, the speaker's 'state of mind' is implicated, and the plaintiff is required to plead the evidentiary facts showing the speaker knew the opinion to be false.")

The subjective falsity standard appeals to common sense: An opinion is "true" if it is actually believed by the speaker at the time it is expressed – regardless of whether it is objectively mistaken, differs from the opinions of others, appears to be unreasonable, or is later changed. Numerous courts evaluating subjective falsity have emphasized this common sense rationale. For example, facts indicating that an opinion was unreasonable, irrational, excessively optimistic, or not borne out by subsequent events are not sufficient to demonstrate that it was subjectively false because a speaker "deliberately misrepresented his actual opinion." *In re Salomon Analyst AT&T Litig.*, 350 F. Supp. 2d 455, 465-67 (S.D.N.Y. 2004). Similarly, an

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opinion is not subjectively false because someone else might have reached "a different opinion than that reached by defendant based on information available to defendant at the time." *Podany v. Robertson Stephens, Inc.*, 318 F. Supp. 2d 146, 154 (S.D.N.Y. 2004) (opinion cannot be false unless "the speaker is knowingly misstating his truly held opinion"); *see also Remec*, 2010 WL 1676741, at *32 (CEO's opinion is not rendered subjectively false because CFO disagreed with the assessment). Finally, an opinion is not rendered false because it is contradicted by later facts, even if those facts cause the speaker to change his opinion. *See In re Ford Motor Co. Sec. Litig. Class Action*, 381 F.3d 563, 572 & n.5 (6th Cir. 2004).

In evaluating *Rubke*, this Court expressed discomfort that the *Rubke* court failed to give meaning to the concept of a subjectively *misleading* opinion. *McGuire III*, 688 F. Supp. 2d at 1244. "The holdings of both [*Rubke* and *Virginia Bankshares*] allow for allegations that the speaker *knew* that the opinion would mislead the intended audience, regardless of whether he believed it." *Id*. (emphasis added). Although not discussed in *Rubke*, a "subjectively misleading" statement is appropriately analyzed by the intersection of *Rubke* and another seminal Ninth Circuit case, *Brody v. Transitional Hospitals Corporation*. *Brody*, 280 F.3d 997, 1006 (9th Cir. 2002); 280 F.3d 997, 1006 (9th Cir. 2002); *Rubke*, 551 F.3d at 1162. *Brody* explicitly rejects the position that "once a disclosure is made, there is a duty to make it complete and accurate." 280 F.3d at 1006 ("No matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not.") Rather, the omission of information only renders a statement misleading if, when viewed in context, it "affirmatively create[s] an impression of a state of affairs that differs in a material way from the one that actually exists." *Id.*; *McGuire v. Dendreon Corp*., No. C07-800MJP, 2008 WL 1791381, at *5-6 (W.D. Wash. Apr. 18, 2008) ("*McGuire I*") (finding plaintiffs failed to sufficiently plead that statements challenged in the original complaint in this case were misleading for failure to mention the existence of the Form 483).

To synthesize *Rubke* and *Brody*, we need only introduce *Rubke*'s language of subjectivity to the *Brody* standard. Thus, an opinion could be *subjectively* misleading if a speaker omits

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information in order to "create an impression of a state of affairs that differs in a material way from the one that [he sincerely "believes"] actually exists." *Brody*, 280 F.3d at 1006; *Rubke*, 551 F.3d at 1162. This standard is consistent with both precedents: To hold that an opinion can be found to be misleading without a subjective element would conflict with *Rubke*, while to find that a speaker must disclose *every* fact that might cause others to disagree with his opinion would conflict with *Brody*'s holding that there is no duty of "completeness." The *Rubke/Brody* test also squares with notions of fairness: A speaker cannot be held liable if he expresses his sincere opinion, and "creates an impression" that reflects the state of affairs as he believes them to be.

B. Plaintiffs cannot prove Dr. Urdal's opinion was subjectively false.

This Court should grant summary judgment as to subjective falsity because uncontested facts indicate that Dr. Urdal sincerely believed on March 29, 2007 that Dendreon had "hosted a good inspection." Dr. Urdal's foremost objective during early 2007 was to get approval for Provenge, and he believed Dendreon had "hosted a good inspection" because the PLI represented progress toward that goal, which would have been a "tremendous achievement" for Dendreon. Declaration of David Urdal[1] ("Urdal Decl.") ¶¶ 2-3; *see also* Transcript from Deposition of David Urdal ("Urdal Dep.") (Ex. 8) at 26:5-27:1; 55:5-11. There is no dispute as to the following facts, which prove that Dr. Urdal believed his statement at the time it was made. (Because the truth of any statement, including an opinion, is determined at the time the statement is made, defendants list only facts that influenced Dr. Urdal as of the date of his statement. *In re Glenfed, Inc., Sec. Litig.*, 42 F.3d 1541, 1549 (9th Cir. 1993).)

First, all the evidence shows that Dr. Urdal genuinely believed Dendreon had done a good job "hosting" the inspection. Dr. Urdal knew that being organized, responsive and professional with the FDA was important to a successful PLI. *See, e.g.*, Urdal Decl. ¶ 6; Declaration of Mary Coon ("Coon Decl.") ¶ 5. During the five days of the PLI, "Dendreon

[1] All declarations are filed herewith in support of the motion for partial summary judgment; all exhibits, including transcript excerpts, are attached to the Declaration of Claire L. Davis.

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hosted five FDA inspectors, answered 260 requests for information covering 90 topics, and provided copies of hundreds of documents" in response to FDA requests. Defendants' Amended Answers and Objections to Plaintiffs' First Set of Interrogatories ("Amended Answers"), Ex 9 at 9. Dr. Urdal was "proud of how the Dendreon team performed during the 2007 PLI." Urdal Decl. ¶ 6. Other members of the Dendreon leadership team concurred that the Dendreon team performed "extraordinarily well." Transcript of Deposition of Andrew Scherer ("Scherer Dep.") (Ex. 47) at 183:3-4; *see also, e.g.*, Declaration of Elizabeth Smith ("Smith Decl.") ¶ 5-6; Coon Decl. ¶ 5. X. Contemporaneous documents support Dr. Urdal's opinion that his team did a good job hosting the inspection. Ex. 10 (email from Dr. Urdal to Dr. Gold on first day of the PLI, indicating "[o]rientation went well"); Ex. 11 (email from Dr. Urdal to Dr. Gold on second day of the PLI, noting "[t]hings are going smoothly"); Ex. 12 (email from Dr. Urdal on last day of the PLI, noting it had been "another smooth day"); Ex. 13 (email from Dr. Urdal observing that Ms. Coon did an "outstanding job at coordinating [and] leading," and "the success of the outcome of the inspection was due to the great support that she received").

During the closeout meeting with the FDA on the last day of the PLI, Dr. Urdal heard the FDA inspectors make many positive comments, including that the "organization was excellent," that they were "very impressed," and that although they "found issues," they thought the organization was "overall very qualified." Ex. 14 (Ms. Coon's notes from the closeout meeting); Coon Decl. ¶ 7. The FDA inspectors also said the Form 483 observations were being brought to Dendreon's attention so they could "respond in a timely manner," and Dr. Keith Wonnacott, the FDA's lead product reviewer for the Dendreon BLA, said "this product is important to FDA and the industry." Ex. 14. The Dendreon team interpreted these comments to indicate that the FDA reviewers had positive feelings about Dendreon, its facility, and the BLA. *See, e.g.*, Urdal Decl. ¶ 6; Declaration of Ernest Bognar ("Bognar Decl.") ¶¶ 6, 7 (noting that FDA inspectors are generally forthright, and that in a closeout for a previous PLI, FDA inspectors had said there were "critical findings," but that the Dendreon closeout was very positive); *see also* Plaintiffs' Expert Witness Supplemental and Rebuttal Report of Richard A. Shupack, Esq., (Ex. 53) at 3

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("FDA inspectors generally make their concerns about a facility known during the inspection. They have no reason to play 'hide the ball.'").

At the conclusion of the PLI, and after receipt of the Form 483, Dr. Urdal attended a dinner with the Dendreon team, during which he and other supervisors thanked the team for a job well done. Urdal Decl. ¶ 15. "The mood at this dinner was celebratory, based on the shared feeling" that Dendreon had "hosted a successful inspection." Ex. 9 at 9 (Amended Answer); *see also* Urdal Decl. ¶ 12; Bognar Decl. ¶ 9; Ex. 15 (Feb. 17, 2007 email from Nicole Provost, recounting dinner as "memorable, with a riotous semi-sober reading of the 483 observations [by a staff member]").

The management team for the PLI included Dendreon's Vice President of Quality Mary Coon, who led Dendreon's PLI effort; Vice President of Regulatory Affairs Elizabeth Smith, who spearheaded Dendreon's communications with the FDA; Vice President of Manufacturing Andrew Scherer; and then New Jersey Plant Manager Ernest Bognar. Representing the key departments of quality, regulatory, and manufacturing, these key members of Dendreon's leadership team were among those people on whom Dr. Urdal relied to inform his judgment. Urdal Decl. ¶ 9. The testimony of these key advisors, as well as their contemporaneous documents, is uniformly supportive of Dr. Urdal's positive impression of the PLI. *See, e.g.*, Ex. 47 at 183:1-22; 184:3-185:2 (Scherer Dep.); Smith Decl. ¶ 5-6; Coon Decl. ¶ 9; Bognar Decl. ¶ 10; Ex. 16 (email from Ms. Coon: "We did great through the [PAI]. Thank you all!"); Ex. 17 (email from Ms. Smith praising employee for his "[n]ice work . . . on the inspection overall"). Documents from that time period indicate these positive feelings were shared by other key Dendreon leaders. *See* Ex. 18 (email from Chris Gunnell, Manager of Quality Assurance, to Ms. Coon after the PLI, praising her for a "great job on the inspection management!"); Ex. 15 (email from Ms. Provost: the "whole team on both coasts handled [the PLI] so well – it was really a testament to planning, logistics, and teamwork"); Ex. 19 (meeting request from Dendreon Chief Financial Officer Greg Schiffman telling team, "Congratulations on the success on the PAI.").

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Second, Dr. Urdal genuinely believed the results of the inspection were "good." Although the challenged opinion is that Dendreon "*hosted* a good inspection," the uncontroverted evidence proves that Dr. Urdal also genuinely believed that the *results* of the inspection were "good." Dr. Urdal believed the Dendreon team dealt effectively with issues as they arose during the inevitable ups and downs that come with an FDA inspection. For example, the Dendreon team effectively addressed some FDA concerns during the PLI so that they did not appear as Form 483 observations. *See, e.g.*, Urdal Decl. ¶ 7; Coon Decl. ¶ 10; Ex. 20 (Dendreon's debriefing notes from the PLI); Ex. 21 (email describing actions to address a potential Form 483 observation).

Based on his industry knowledge and experience, and that of his advisors, Dr. Urdal knew the FDA routinely issues Form 483s following PLIs. Ex. 9 at 10 (Amended Answers); Urdal Decl. ¶ 10; Ex. 47 at 186:4-187:3 (Scherer Dep.); Bognar Decl. ¶¶ 5-6; Smith Decl. ¶ 3; Coon Decl. ¶ 4. As a result, Dr. Urdal "fully expected" that Dendreon would receive a Form 483, "even if the inspection went very well." Urdal Decl. ¶ 8. When he evaluated the Form 483 Dendreon received, Dr. Urdal was pleased that the observations were limited in number; that they were issues he believed Dendreon could address in a timely way; and that none of them were "showstoppers" that would impede approval. Ex. 9 at 10 (Amended Answers); Urdal Decl. ¶ 8. Specifically, none of the observations "questioned the quality of the product being manufactured or the adequacy of [Dendreon's] basic manufacturing system." Urdal Decl. ¶ 8. Instead, the observations were issues Dr. Urdal believed would be relatively straightforward to address, "such as manufacturing logistics, the need to submit additional information or data to the FDA, and the need to clarify for the FDA some aspects of our manufacturing process." *Id.*; Ex. 22 (Dendreon's Form 483).

Contemporaneous emails from Dr. Urdal confirm the sincerity of his opinion that the inspection was "good." On February 25, 2007, nine days after the PLI, Dr. Urdal wrote of the "success of the outcome of the inspection" to Mr. Schiffman, indicating that it "shines the spot light on the whole organization and the organization and the individuals deep within it did well.

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[Dendreon's facility, validations, and systems] are standing up to the close scrutiny of FDA review and inspection." Ex. 13; *see also, e.g.*, Ex. 13 (Feb. 27, 2007 email from Dr. Urdal: the Form 483 will not lead to "any extraordinary financial consequences"); Ex. 23 (email from Dr. Urdal to Dr. Gold one week after the PLI noting "[a]ll is well"). In fact, Dr. Urdal pushed the Dendreon team to draft the responses to the Form 483 observations as quickly as possible, because he was confident of Dendreon's ability to respond to the observations, and wanted to keep the approval process moving quickly. Ex. 8 at 44:15-17 (Urdal Dep.); Urdal Decl. ¶ 11; X; Coon Decl. ¶ 10; Ex. 23 (email from Dr. Urdal describing the importance of responding promptly to the Form 483).

Dr. Urdal's belief that the inspection was successful was reinforced by Dendreon's communications with the FDA between the PLI and March 29, 2007. Dr. Urdal knew Dendreon was in regular contact with the FDA after the PLI, and that these conversations were productive and positive. Urdal Decl. ¶ 15; Smith Decl. ¶ 8; *see also* Ex. 24 (FDA minutes of a May 9, 2007 phone call during which Dr. Wonnacott praised Dendreon's "positive interactions" with the FDA). For example, Dr. Urdal knew the FDA had requested weekly conference calls following the PLI, which Ms. Smith told him demonstrated the FDA's desire to work closely with Dendreon to immediately "deal with any issues that might pop up" so they would not delay the approval process. Ex. 25 (Feb. 23, 2007 email from Ms. Smith, regarding FDA's desire to schedule weekly calls); Urdal Decl. ¶ 15; Smith Decl. ¶ 8.

Dr. Urdal's opinion of the PLI was also bolstered by Dendreon's interactions with the FDA regarding the Form 483 in the period before the Advisory Committee meeting. First, Dendreon sent the FDA responses to the Form 483 observations within ten business days of the PLI. Ex. 9 at 10-11 (Amended Answers); Ex. 26 (Dendreon's March 2, 2007 responses to the Form 483). Dr. Urdal was "very pleased" with Dendreon's response to the Form 483, and thought it was both "timely" and "comprehensive." Ex. 27 (email from Dr. Urdal regarding the Form 483 response). Ms. Coon, who led the team that drafted the Form 483 response, and briefed Dr. Urdal on this effort, thought the March 2, 2007 responses met the Company's

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outlined objectives, including providing action-oriented corrective steps sufficient to quickly address each observation. Coon Decl. ¶ 11; Ex. 28 (outline of Dendreon's strategy for responding to the Form 483). Dr. Urdal and his team believed that with this response, Dendreon had proposed an action plan sufficient to resolve each observation in advance of the May 15, 2007 PDUFA date. Urdal Decl. ¶ 11; Coon Decl. ¶ 10; Smith Decl. ¶ 7; Bognar Decl. ¶ 8.

On March 23, 2007, Dr. Urdal participated in a conference call during which FDA representatives told Dendreon that they believed all but one of its proposals to address the Form 483 observations could be accomplished without major amendments to the BLA that might delay the PDUFA date. Urdal Decl. ¶ 16; Smith Decl. ¶¶ 9-10; Coon Decl. ¶ 11; Ex. 29 (Dendreon's minutes from the March 23, 2007 conference call, noting that with one exception, "FDA did not believe that any of the responses to their questions would require major amendments to resolve"); Ex. 30 (Ms. Coon's notes); Ex. 31 (Ms. Krstulich's notes); Ex. 32 (FDA minutes, indicating there was "*one* issue with regard to Dendreon's response to the 483") (emphasis added). In regard to the remaining observation – Observation 1 – the FDA indicated that the data that Dendreon proposed to submit as part of its initial response could be considered a major amendment to the Provenge BLA. In response, Dendreon proposed that the FDA grant Dendreon an initial license that limited commercial production to the level the FDA believed was supported by existing data, thus eliminating the possible approval delay due to Observation 1, and allowing for Dendreon to submit additional data quickly following approval to lift any production limitations. Ex. 8 at 50:15-51:1 (Urdal Dep.); Urdal Decl. ¶ 16; Smith Decl. ¶¶ 9-10; Ex. 29; Ex. 30; Ex. 31; Ex. 32; Ex. 33 (email from Ms. Krstulich describing Dendreon's proposal). FDA representatives indicated that they were open to this proposal, but could not discuss the details until a call scheduled after the Advisory Committee meeting – although they indicated that Dendreon's proposed timeline for additional submissions would probably be acceptable. Urdal Decl. ¶ 16; Smith Decl. ¶¶ 9-10; Ex. 29; Ex. 30; Ex. 31; Ex. 32 (FDA notes, indicating willingness to consider Dendreon proposal). Dr. Urdal left the March 23, 2007 meeting with a "sense of optimism" that Dendreon would be able to resolve Observation 1 by the

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PDUFA date. Ex. 8 at 54:15-20 (Urdal Dep.); *see also* i*d.* at 50:15-51:1. In addition, both Dr. Urdal and Ms. Smith – Dendreon's lead liaison with the FDA – felt that the call confirmed the FDA's commitment to working with Dendreon to resolve all remaining issues, including the Form 483 observations, in advance of the PDUFA date. Urdal Decl. ¶ 17 (it appeared FDA wanted to expedite resolution of remaining issues, giving a "sense of increased comfort" that Dendreon was on the path to resolve all the Form 483 observations); Smith Decl. ¶¶ 10-11 (indicating her impression that the FDA wanted to work toward a resolution of all observations, which was confirmed during subsequent conference calls during which these issues were resolved).

During Dr. Urdal's deposition, plaintiffs pointed to two documents they implied suggested that Dr. Urdal did not believe the PLI had gone well. Ex. 8 at 20:15-24:24 (Urdal Dep.). Neither document controverts the evidence listed above. First, plaintiffs asked Dr. Urdal about the minutes of a March 2, 2007 Dendreon board of directors meeting, which indicate Dr. Urdal gave the Board an update on the PLI: "Dr. Urdal reported . . . that the top three 483 issues regarding the manufacturing facility were: the Company's ability to do 12 lots concurrently; whether the Company will have the resources and staff to produce Provenge commercially; and establishing a clear chain of identity for the product in the form of bar coding." Ex. 34; Ex. 8 at 21:20-22:14 (Urdal Dep.). During his deposition, Dr. Urdal explained that these minutes did not reflect his full statement to the Board: "I know at that meeting I gave them an update of my impressions of how the inspection had gone and a sense of optimism that we saw no issues that we wouldn't be able to resolve before [the] PDUFA date was scheduled to occur in May." Ex. 8 at 22:1-6 (Urdal Dep.); *see also* Urdal Decl. ¶ 13; Transcript from Deposition of Mitchell Gold ("Gold Dep.") (Ex. 51) at 19:6-10 ("[W]hat I do remember Dave sharing [with the board] was that we hosted a good inspection, and . . . none of the observations from the inspection were going to limit our ability to receive approval of the product."). Dr. Urdal explains in his declaration that the minutes "paraphrase" his remarks, and do not reflect the full content of the report that he gave to the Board. Urdal Decl. ¶ 13; Ex. 34 (minutes from March 2, 2007 board

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meeting). Either way, the indication that Dr. Urdal identified the "top three" Form 483 observations for the Board are not inconsistent with his expressed belief that *none* of the observations would interfere with the approval of Provenge by the May 15, 2007 PDUFA date. Indeed, it is uncontroversial that some observations from a Form 483 will generally be more important than others. In addition, the minutes of the Board meeting are consistent with Dr. Urdal giving a positive report about the PLI, as they do not reflect *any* continuing discussion or concern about the Form 483 observations on the part of the Board. *Id*. (reflecting Dr. Urdal's brief report on the PLI, followed by extensive discussion of other topics); Urdal Decl. ¶ 13.

Similarly, a rough recap of a due diligence call with Pfizer, which took place two weeks *after* Dr. Urdal's March 29, 2007 statement, does not raise any genuine issues in regard to the veracity of his publicly-stated opinion. *See Glenfed*, 42 F.3d at 1549 (subsequent comments do not show falsity of earlier statement). Even if the phone log did represent a contemporaneous statement by Dr. Urdal, it is merely a shorthand version of what was discussed, which is not intended as a verbatim recital. Ex. 35 (reflecting that Dr. Urdal said "DNDN had 9 483's, 6 are minor, 3 are major and deal with capacity issues"). Plaintiffs cannot rely on the significance of any particular word used in such a summary. And Dr. Urdal has made clear that he did not believe, and would not have said, that the Form 483 observations were "major" in a broad sense, but if, in fact, he used that word, it was only to compare the relative importance of the observations in the Form 483 to one another. Urdal Decl. ¶ 14. Once again, such a comparison is not inconsistent with the fact that he believed none of the observations would have prevented approval by the May 15, 2007 PDUFA date, or that he thought the PLI was "good." And the log does not reflect any additional discussion or concerns over the PLI. Ex. 35.

The above facts are not subject to genuine dispute. As a result, plaintiffs cannot produce evidence sufficient to support a jury finding that Dr. Urdal did not honestly believe on March 29, 2007, that Dendreon had "hosted a good inspection."

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C. Plaintiffs cannot prove Dr. Urdal's opinion was subjectively misleading.

Under the standards of *Brody* and *Rubke*, Dr. Urdal's March 29, 2007 statement is subjectively misleading if he omitted information that he knew "affirmatively created an impression of a state of affairs that differs in a material way from the one that [he believed] actually exist[ed]." *Supra* pp. 7-8. This standard contains two crucial concepts: 1) under *Rubke*, whether a statement is misleading must be judged "subjectively," in the context of the state of affairs as the speaker *believed them to be*; 2) under *Brody*, there is no "completeness" rule, so an omission only renders a statement misleading if it creates a *materially* false impression of the overall state of affairs as the speaker understood them. With these elements in mind, the *Brody* analysis requires that the full context of Dr. Urdal's statement be considered:

> **[Dendreon Analyst] Charles Duncan:** OK, and then, final questions with regard to timelines, do you anticipate having to submit any additional information with regard to kind of the validation of your manufacturing processes?
>
> **Mitchell Gold:** Sure. One of the things that we did as part of our biologic license application with the FDA, in particular the CMC section, was to submit a lot of manufacturing data. And as part of that, the FDA came out and we hosted them for pre-approval inspections at our Hanover, New Jersey facility.
>
> **Charles Duncan:** OK. And those facilities obviously passed the muster? Or, you know, can you give us more insights on that?
>
> **[Dr. Urdal]:** Actually – those are activities that we'll be discussing with the agency between now and the PDUFA date. **So, it's actually we hosted a good inspection, I think,** and we'll have ongoing discussions with them between now and May 15 to finish the CMC section.
>
> Ex. 1 at 4-5 (emphasis added).

This exchange illustrates Dr. Urdal's attempt to frame a fair answer to an unscripted inquiry. As an initial matter, it is absurd to allege that Dr. Urdal "interrupted" Dr. Gold – he fielded the question because as Dendreon's Chief Scientific Officer and head of manufacturing, he usually answered such questions. Urdal Decl. ¶ 18. In answering, Dr. Urdal tried to offer the "insight" requested, while fairly characterizing the state of affairs in relationship to the PLI. Accordingly, in addition to providing his insight that Dendreon had "hosted a good inspection," Dr. Urdal also accurately revealed that Dendreon was having continuing discussions with the

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FDA about inspectional issues, and made clear that these discussions were necessary in order to "finish" the CMC section of the Provenge BLA. Ex. 1. Dr. Urdal did not make a conscious decision to omit the term "Form 483" from his answer. Urdal Decl. ¶ 19. Dr. Urdal understood the Form 483 to be the "first step in an ongoing discussion with the FDA about inspectional issues," and although it is not customary in the industry to reveal the details of such discussions, Dr. Urdal did make clear that the discussion was ongoing, and that the FDA had not finished its review of the inspectional issues. Ex. 1 at 6; Urdal Decl. ¶ 19; Ex. 51 at 15:18-24 (Gold Dep.). Most significantly, there is *no* evidence that the existence of the Form 483 changed Dr. Urdal's view that Dendreon had "hosted a good inspection," or that the omission of this phrase from his answer created a *materially* false impression of the state of affairs as he believed them to be.

Evidence of subsequent *inconsistent* statements is not sufficient to show an opinion was subjectively false or misleading. However, subsequent *consistent* statements may demonstrate veracity. In this instance, subsequent statements by Dr. Urdal regarding the PLI were consistent with both the opinion he expressed on March 29, 2007, as well as with the overall "impression of the state of affairs" that he conveyed. For example, during the May 10, 2007 conference call following receipt of the CRL, Dr. Urdal mentioned the Form 483 observations as an *example* of a CMC item listed in the CRL, even though the script for the conference call did not call for him to do so. Ex. 36 at 13 (transcript of May 10, 2007 call); Ex. 37 (script prepared for May 10, 2007 call). This casual mention of the Form 483, in a question that did not necessarily call for that response, demonstrates a lack of any conscious effort by Dr. Urdal to conceal the Form 483. And even though Dr. Urdal used the words "Form 483" during his May, 10, 2007 statement, his description of the overall situation was entirely consistent with his March 29, 2007 opinion: He mentioned the Form 483, said Dendreon had been addressing those observations "quite effectively," and said he believed the observations were "well in hand" and would not "delay the approval process from a manufacturing point of view." Ex. 36 at 13.

When Dr. Urdal's statement is evaluated under the appropriate standard of law, plaintiffs cannot make any factual showing sufficient to support a finding that it was subjectively

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misleading. They cannot produce facts sufficient to show, for example, that Dr. Urdal deliberately hid the existence of the Form 483 from investors because he viewed it as an adverse material event, or that Dr. Urdal believed that not using the technical term "Form 483" created an impression of a state of affairs that was different from what he believed them to be. For these reasons, summary judgment should be entered against plaintiffs on this issue.

D. Plaintiffs cannot show Dr. Gold should be held liable for Dr. Urdal's opinion.

Dr. Gold did not make any allegedly false or misleading statements. Although they phrase it as a "duty to correct" claim, plaintiffs essentially seek to hold Dr. Gold liable for Dr. Urdal's opinion by reason of Dr. Gold's position as Dendreon CEO, and his participation in the March 29, 2007 conference call. *See* TAC ¶ 77; MAC ¶ 72. However, allegations against a non-speaking defendant are inadequate to state a claim if there is insufficient evidence to show the defendant was involved in the alleged fraud. For example, in *Pegasus Holdings v. Veterinary Centers of America, Inc.*, the court rejected the idea that a defendant should be held liable merely because he attended a meeting in which someone else made alleged misrepresentations, when no facts suggested his involvement in fraud. 38 F. Supp. 2d 1158, 1164 (C.D. Cal. 1998) (finding "allegations of stock ownership and attendance at certain meetings is not enough to establish a functional relationship to a fraudulent scheme").

The allegations of liability for Dr. Gold are even more tenuous because Dr. Urdal's statement is an opinion – plaintiffs thus are seeking to hold Dr. Gold liable for the alleged misstatement of someone else's subjective viewpoint. This is not the kind of obviously false statement that can give rise to a duty to correct. Nor can plaintiffs support a finding that Dr. Gold did not believe Dr. Urdal's statement was both true and a fair depiction of the existing state of affairs. Dr. Urdal was the senior official at Dendreon with oversight of manufacturing issues. Urdal Decl. ¶ 18. Dr. Gold thus depended on Dr. Urdal's evaluation of these technical issues. *Id.* Indeed, although Dr. Gold also received consistent information from other sources, much of Dr. Gold's knowledge about the PLI came from Dr. Urdal. Urdal Decl. ¶ 18; Ex. 51 at 82:12-17 (Gold Dep.). And the opinion Dr. Urdal communicated during the March 29, 2007 call

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was consistent with information that he had communicated to Dr. Gold previously. Ex. 51 at 19:5-9 (Gold Dep.). There is no evidence to suggest that Dr. Gold held an opinion different from the one Dr. Urdal held, or knew facts that caused him to doubt the veracity of this opinion. Finally, as with Dr. Urdal, Dr. Gold's subsequent statements are consistent with the opinion expressed on March 29. Ex. 36 at 14 (transcript of May 10, 2007 conference call, reflecting Dr. Gold's remark that the FDA agreed Dendreon could "easily address" the Form 483 observations).

Because plaintiffs cannot produce any material facts demonstrating that Dr. Gold had a "duty to correct" Dr. Urdal's statement, or that he believed Dr. Urdal's statement to be false or misleading, summary judgment should be granted on the false statement claim against Dr. Gold.

III. SUMMARY JUDGMENT SHOULD BE GRANTED ON LOSS CAUSATION.

Summary judgment should be granted on the independent and sufficient ground that plaintiffs cannot show facts sufficient to establish loss causation. Uncontroverted facts demonstrate that the proximate cause of plaintiffs' loss was the FDA's finding that the clinical data was insufficient to support the approval of Provenge in 2007. The FDA's finding that the clinical data was insufficient has no causal connection to either Dr. Urdal's alleged false statement regarding the PLI, or the Form 483, the "risk" allegedly concealed by this statement. As a result, plaintiffs cannot show loss causation as a matter of law, and summary judgment should be granted on this essential element of their claim.

A. Plaintiffs must show a causal connection between the statement and the loss.

In *Dura Pharmaceuticals, Inc. v. Broudo*, the Supreme Court conclusively established that securities fraud plaintiffs must show a "causal connection between the material misrepresentation and the loss." 544 U.S. 336, 342 (2005); *see also McGuire I*, at *10. This causal connection, often referred to as "loss causation," is distinct from the separate element of "transaction causation," which requires plaintiffs to establish that the stock price at the time of their purchase was inflated because of the alleged misrepresentation. *Dura*, 544 U.S. at 341, 342; *see also Binder v. Gillespie*, 184 F.3d 1059, 1065-66 (9th Cir. 1999). In *Dura*, the Supreme

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Court rejected the proposition that this purchase inflation was sufficient to show plaintiff's economic loss:

> When the purchaser subsequently sells such shares, even at a lower price, that lower price may reflect, not the earlier misrepresentation, but changed economic circumstances, changed investor expectation, new industry-specific or firm-specific facts, conditions, or other events, which taken separately or together account for some or all of that lower price. *Id.* at 342-43.

Rather, *Dura* requires securities fraud plaintiffs to prove that the misrepresentation is the "proximate cause" of their loss. *Id.* at 346; *Binder*, 184 F.3d at 1066; *In re Wash. Mut., Inc. Sec., Deriv. & ERISA Litig.*, No. 2:08-MD-1919 MJP, 2009 WL 3517630, at *22 (W.D. Wash. Oct. 27, 2009) ("Plaintiff must allege that the misrepresentations were the proximate cause of the losses suffered.")

To define "proximate cause," the courts have looked to basic principles of tort law. *Dura*, 544 U.S. at 344 (*citing* W. Page Keeton, et al., *Prosser and Keeton on the Law of Torts* § 110, p. 765 (5th ed. 1984) ("Prosser & Keeton on Torts")); *Binder*, 184 F.3d at 1066 (the loss causation requirement is "equivalent to proximate causation in tort"). Thus, "an act or omission is not regarded as a cause of an event if the particular event would have occurred without it." *Prosser & Keeton on Torts*, § 110, p. 265. Or, in the words of the standard "but for" formulation of proximate cause: "The defendants' conduct is a cause of the event if the event would not have occurred but for that conduct; conversely, the defendants' conduct is not a cause of the event, if the event would have occurred without it." *Id.*

B. There is no evidence connecting the alleged misstatement with the loss.

As the standards above make clear, it is not sufficient for plaintiffs to plead that "Dendreon's stock price would have never risen as high as it did" if Dr. Urdal had mentioned the Form 483 in his March 29, 2007 statement. TAC ¶ 99; MAC ¶ 98. Plaintiffs must also show loss causation by proving that either 1) their loss was caused by the market learning the "truth" that had allegedly been concealed in the March 29, 2007 statement, or alternately 2) their loss was caused by a materialization of the concealed risk – i.e. the manufacturing issues in the Form

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483. *In re Daou Sys., Inc.*, 411 F.3d 1006, 1025-27 (9th Cir. 2005); *Ray v. Citigroup Global Markets, Inc.*, 482 F.3d 991, 995 (7th Cir. 2007).

1. Plaintiffs cannot show loss causation through a corrective disclosure, because Dendreon stock *increased* after disclosure of the Form 483.

In claiming that they suffered losses after the allegedly concealed information was revealed to the market through a corrective disclosure, plaintiffs rely on two public statements by Dendreon: the May 9 press release announcing the CRL and the FDA's request for additional clinical data, and the May 10 public conference call during which Dr. Urdal disclosed the Form 483. TAC ¶¶ 87, 89; MAC ¶¶ 81, 85. As a matter of law, neither announcement can satisfy the *Dura* standard.

The essential facts are not in dispute. Rather than approving Provenge in 2007, the FDA issued the CRL on May 8, 2007. Ex. 38. The CRL was first disclosed by Dendreon's May 9, 2007 press release, which announced that the FDA had issued a CRL requesting additional clinical data concerning efficacy. Ex. 39; TAC ¶ 87; MAC ¶ 81. The May 9, 2007 press release also stated: "The FDA has also requested additional information with respect to the chemistry, manufacturing and controls (CMC) section of the BLA, which the Company believes it can supply to the FDA in a timely manner." TAC ¶ 87; MAC ¶ 81; Ex. 39. The press release made no reference to the PLI or the Form 483. The price of Dendreon stock closed at $6.33 on May 9, 2007, down from $17.74 on May 8. TAC ¶ 88; MAC ¶ 82. The next day, Dendreon held a public conference call after the market closed. TAC ¶ 89; MAC ¶ 85; Ex. 36. During that call, Dr. Urdal disclosed for the first time that Dendreon had received a Form 483 after its February PLI. TAC ¶ 89 MAC ¶ 85; Ex. 36 at 13. On May 11, the first trading day after this announcement, the price of Dendreon stock closed at $6.11, up from $5.54. Ex. 40.

Plaintiffs cannot show the May 9, 2007 press release corrected Dr. Urdal's allegedly false or misleading statement, because the May 9, 2007 press release neither mentioned nor alluded to either the PLI or the Form 483. Although plaintiffs are not required to point to an overt admission of fraudulent conduct, they must show that the "practices that the plaintiff contends are fraudulent were revealed to the market and caused the resulting losses." *Metzler*, 540 F.3d at 1063-64. Here,

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they cannot do so. Plaintiffs glossed over this glaring problem at the pleading stage, by claiming that the reference to the FDA's request for information on the CMC section amounted to a disclosure of the observations in the Form 483. *See McGuire I*, at *10 (declining to dismiss plaintiffs' allegations of loss causation, because there are no heightened pleading standards on that element, and the Court accepted as true plaintiffs' allegations that the May 9, 2007 press release revealed "the CMC issues identified in the Form 483" and made public "the FDA's previously undisclosed CMC concerns – the ones identified in the Form 483.") Now, the uncontroverted evidence demonstrates this is not true. The first item under the CMC section of the CRL indicates that "[o]utstanding issues from [Dendreon's] pre-license inspection, dated February 12-16, 2007, have yet to be resolved." Ex. 38. The other six issues in the CMC section of the letter, including nine additional subparts, are not related to the inspection or the Form 483. *Id.*; Urdal Decl. ¶ 21. Thus, while the Form 483 observations are properly classified as CMC issues, so are several other topics in the CMC section of the CRL, which have nothing to do with the PLI or the Form 483. Urdal Decl. ¶ 21; Ex. 38 (CRL, listing CMC items 2-7 referring to shipping validation, the stability of the aphaeresis product, manufacturing comparability data, and analytical testing methods).

Thus, the content of the CRL itself shows that Dendreon's reference in the May 9, 2007 press release to the FDA's request for additional information on the CMC section does *not* constitute a disclosure of the existence of inspectional issues or the Form 483. In fact, there is no reason to believe the May 9 disclosure would have been any different if the CRL had not included Item 1, related to inspectional issues. As such, the May 9, 2007 press release cannot constitute a corrective disclosure of Dr. Urdal's allegedly misleading statement that Dendreon "hosted a good inspection," because it did not provide investors with notice that there was a Form 483, or with *any other information* about whether the PLI was, in fact, good or bad. Plaintiffs cannot prove "loss causation through 'euphemism,'" by using unwarranted inferences to contend that a statement that did not disclose the alleged fraud or the underlying facts was nonetheless a corrective disclosure. *Metzler*, 540 F.3d at 1065 (rejecting plaintiffs' inferences that an article about the investigation of

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improprieties at one campus and a negative earnings announcement collectively represented a revelation of the "true facts" regarding widespread improprieties at several schools).

On the other hand, the Form 483 *was* disclosed during Dendreon's May 10, 2007 conference call, during which Dr. Urdal mentioned the CRL's reference to inspectional issues as one example of the CMC issues listed in the letter. Plaintiffs concede this is the first time the Form 483 was disclosed. TAC ¶ 89; MAC ¶ 85. However, following this discussion, the price of Dendreon stock *increased*. Ex. 40. Plaintiffs cannot state a claim for economic loss as the result of an *increase* in the value of Dendreon stock, or make a causal connection between an earlier loss and a later disclosure. *Daou Sys.*, 411 F.3d at 1026-27 (rejecting claims of economic loss that occurred prior to the corrective disclosures, since they "cannot be considered causally related").

2. Plaintiffs cannot show the realization of hidden risks caused their loss.

Plaintiffs may attempt to establish loss causation with a theory that the materialization of the allegedly concealed risk of the Form 483 was the cause of their economic loss. To make this showing, plaintiffs would have to introduce sufficient facts to show that the Form 483 was the proximate cause of the alleged loss that occurred on May 9, 2007 the day after the CRL was announced. Uncontroverted facts show the following factors contributed to this alleged loss: 1) the FDA decision to issue a CRL on May 8, 2007, rather than approving Provenge; 2) the way in which the CRL was characterized in Dendreon's May 9, 2007 press release; and 3) the market's reaction to the CRL, as it was characterized by Dendreon. TAC ¶ 88 ("On May 9, 2007, after the disclosure of the CMC and efficacy issues, Dendreon's stock price plummeted to $6.33, causing substantial losses to plaintiffs[.]"); *see also* MAC ¶ 82. Thus, the key question becomes, what was the proximate cause of these three events?

Plaintiffs assert that the Form 483 observations, standing alone, would have delayed FDA approval in 2007. However, the evidence shows the contrary – it demonstrates that Dendreon had either resolved all of the observations, or come to agreement with the FDA about how to resolve them, well in advance of the May 15, 2007 PDUFA date. Indeed, deposition testimony, expert reports, records of communications between Dendreon and the FDA, and other documents

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all indicate that none of the Form 483 observations would have delayed approval, had the FDA decided that the Provenge clinical efficacy data was sufficient for licensure. But the Court need not reach this issue, or explore the technical complexities of the Form 483, in order to rule on this motion. This is because it is uncontroverted that the deficiencies in Dendreon's clinical trials, and other CMC issues unrelated to the PLI, *would have*, standing alone, caused the market to decline to the same level. As discussed above, plaintiffs cannot establish that the Form 483 observations were the proximate cause of their loss, if "but for" those observations, the loss would have still occurred. *Prosser & Keeton on Torts*, § 110, p. 265 ("an act or omission is not regarded as a cause of an event if the particular event would have occurred without it").

First, it undisputed that the deficiencies in the Provenge clinical data were an independent and sufficient reason for the FDA to issue the CRL in 2007. In other words, the FDA's clinical concerns would have led to the CRL regardless of the existence of the Form 483. For proof of this proposition, we need look no farther than the CRL itself, which indicates that the clinical data failed to support effectiveness claims based on either overall survival or time-to-disease progression. Ex. 38. Concluded the FDA: "*Therefore the submitted clinical data were not sufficiently persuasive to support licensure at this time.* Please submit additional clinical data in support of your efficacy claim." *Id.* (emphasis added). Subsequent statements from the FDA confirm that it viewed the deficiencies in clinical efficacy data to be an insurmountable obstacle to approval in 2007. *See, e.g.*, Ex. 3 at 17 (Summary Basis for Regulatory Action issued by the FDA after Provenge was approved in 2010, explaining: "After complete review of the original BLA submission, the FDA determined that the efficacy result in the original application was not statistically persuasive. Therefore, the FDA issued a complete response letter requiring submission of the results of Study D9902B before licensure."); Ex. 41 (FDA Q&A following Provenge approval in 2010, noting that Provenge was approved because Dendreon answered efficacy concerns by completing the IMPACT trial). These documents are consistent with the views held by Dendreon's management team, which understood that clinical concerns drove the FDA's decision to issue the CRL – and had long realized that it would be

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difficult to gain FDA approval in 2007 with the limited clinical data that existed on efficacy. Urdal Decl. ¶ 3; Urdal Decl. ¶ 5 ("I knew that the FDA did not normally license products under these conditions, but was hopeful that the FDA would nonetheless approve Provenge, because it was designed to serve patients with terminal disease who had few other treatment options."); Ex. 51 at 60:2-15 (Gold Dep).[2] Finally, even the experts retained by the plaintiffs do not disagree that the clinical efficacy concerns, by themselves, would have led the FDA to issue the CRL in 2007. Transcript of Deposition of James T. O'Reilly ("O'Reilly Dep.")(Ex. 52) at 30:6-45:9; Transcript of Deposition of Richard Shupack ("Shupack Dep.")(Ex. 45) at 50:5-13-56:23.

Second, there are no facts to suggest that the language of Dendreon's May 9, 2007 press release would have been different in the absence of the first item in the CRL, mentioning inspectional issues. The May 9, 2007 press release was brief and to the point, disclosing the CRL, the request for additional clinical data, and the FDA's request for additional information related to CMC issues. This precise disclosure would remain accurate in the absence of the item in the CRL referring to inspectional issues, as long as the CRL still retained its request for additional clinical data, and at least one of the six CMC issues not related to the PLI.

Third, since issuance of the CRL, and the disclosure of the CRL, would not have been any different absent the Form 483, it follows that the market reaction would also have been the same. The market reacted not only to the CRL, but to the fact that because the FDA found the clinical data supporting Provenge to be insufficient, approval was likely to be delayed by as long as four years. The market knew the Advisory Committee recommended that Dendreon continue to enroll patients in its IMPACT trial even if it received approval in 2007, and understood that when the FDA requested additional clinical data, it was likely referring to the results of this trial. Ex. 2 at 344; 370-373 (Advisory Committee discussion of IMPACT trial). Indeed, these facts

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[2] These views were confirmed when, after the CRL, FDA representatives indicated that clinical concerns were the basis for its decision not to approve Provenge, and that the CMC issues – including issues related to the PLI – would not have prevented approval. *See, e.g.*, Smith Dep. at 100:14-101:6; Smith Decl. ¶ 12; Ex. 24 (FDA notes from May 9, 2007 conversation between Ms. Smith and Dr. Wonnacott); Gold Dep. at 89:13-15; 90:1-5; Ex. 42 (FDA notes from May 9, 2007 call between Dendreon representatives and the FDA's Dr. Stephanie Simek).

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were disclosed in the same March 29, 2007 call in which Dr. Urdal said Dendreon had "hosted a good inspection." Ex. 2 at 844-85. Since the IMPACT trial was aimed at collecting data on survival, it could not be completed until a certain number of trial participants died, which Dendreon had publicly estimated was likely to take until 2010. Ex. 2 at 84-85; Ex. 1 at 15. As a result, the market equated news that the FDA needed more efficacy data to a potential delay in approval of as long as four years. Ex. 43 (*Seattle Times* article indicating that the FDA's request for more efficacy data might delay the introduction of Provenge "at least until 2011"); Ex. 44s (*Wall Street Journal* article referring to IMPACT trial, but noting that it could take until 2010 for final results).

These facts show that "but for" the Form 483 (and the alleged misstatement), plaintiffs would have suffered exactly the same loss they allege: The FDA still would have issued a CRL, which Dendreon would have described in the same way, to which the market would have reacted in the same fashion, causing Dendreon's stock price to fall to the same level. By the standards of proximate cause, it is thus apparent that plaintiffs cannot establish that the "materialized risk" of the Form 483 caused their economic loss. Since they also cannot show any causal connection between the disclosure of the Form 483 and their alleged loss, plaintiffs are unable, as a matter of law, to demonstrate loss causation, and summary judgment should be entered on this basis.

CONCLUSION

For the reasons explained above, plaintiffs cannot produce evidence sufficient to establish the elements of falsity and loss causation, which are essential to maintain a Section 10(b) claim, and summary judgment should be granted as to the first and second claims of relief in *McGuire v. Dendreon* and *Mountanos v. Dendreon*.

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Dated: June 21, 2010

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CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2010, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record who receive CM/ECF notification.

Dated: June 21, 2010

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